DISPOSITION: January 12, 1949. Default decree of condemnation and destruction.

3548. Misbranding of Spectro-Chrome. U. S. v. 1 Device, etc. (F. D. C. No. 16892. Sample No. 16921–H.)

LIBEL FILED: On or about August 14, 1945, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 2, 1945, from Newfield, N. J., by Dinshah P. Ghadiali.

PRODUCT: 1 *Spectro-Chrome* device, together with an assortment of written, printed, and graphic matter. (The device is described in notices of judgment on drugs and devices, No. 3149.)

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label and in the accompanying labeling were false and misleading. (See above-referenced notice of judgment for the nature of the misbranding.)

DISPOSITION: May 17, 1950. Upon motion of the Government, the case was dismissed.

3549. Misbranding of Therm-Massage infrared heat applicator. U. S. v. 143 Cartons, etc. (F. D. C. No. 24706. Sample No. 32388–K.)

LIBEL FILED: April 8, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about March 11, 1948, by Sibert & Co., from Newark, N. J.

PRODUCT: 143 cartons each containing 1 device labeled "Therm-Massage Infra-Red Heat Applicator" and a circular bearing the same name; also, in shipping cases, 39 additional copies of the above circular and copies of circulars entitled "Heat Massage Those Pains Away," "Amazing New Scientific Invention," "1st Ad, July 1st for Beauty Aid," and "Earn Extra Profits," and copies of display cards entitled "Relieve Pain Quickly" and "Therm-Massage Infra-Red." The device, together with the accompanying labeling, was at San Francisco, Calif.

Examination showed that the device consisted of two pieces of molded bakelite, one serving as the handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the circulars and the display cards accompanying the device contained certain statements which were false and misleading. These statements represented and suggested that the device would be effective in the cure, mitigation, and treatment of headache, sinus, muscular aches, sprains, cramps in feet or legs, stiff neck or stiff joints, colds, backache, rheumatism, aching muscles, arthritis, aching joints, neuritis, and neuralgia; that the device would be efficacious to reach down into aching muscles and joints, to bring new comfort to tortured nerves, to relax sore muscles, and to make aching nerves and joints feel better; that the device would be effective in the cure, mitigation, and treatment of foot pains, head pains, nerve pains, back pains, stiff and sore shoulders and back muscles, rheumatism, toothache, sprains and bruises, and sprained ankle; that it would cause the pain to disappear from an injured hand and enable one to get a good night's sleep; that it would be effective in the cure, mitigation, and treatment of any aches or pains; that it would relieve the stiffness in the neck muscles after a tonsillectomy; that it would relax the tiny muscles of the face, throat, and neck,

and prevent the formation of wrinkles; that it would stimulate the flow of blood into the tiny capillaries lying just under the surface and remove and eliminate the waste products accumulated in such capillaries; that it would be effective in the cure, mitigation, and treatment of sallow, muddy complexions and skim blemishes; and that it would penetrate tissues and bone, invigorate the entire system, bring fresh food to nerves and tissues, and stimulate the system to more vigorously fight disease germs. The device was not capable of fulfilling the promises of benefit stated and implied.

DISPOSITION: December 21, 1948. Ralph Clinton, San Francisco, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration. Reconditioning resulted in the destruction of all objectionable leaflets and circulars.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3541 TO 3549

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3542, 3544, 3545) Injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1952

Issued March 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3550–3580

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 19, 1952.*

CONTENTS*

*For presence of a habit-forming narcotic without warning statement, see Nos. 3556–3559, 3561; omission of, or unsatisfactory, ingredients statements, Nos. 3556, 3558, 3560–3564; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3554, 3556, 3557, 3559–3563, 3579.

988985—52——1

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3550. Action to enjoin and restrain violations of Sections 301 (a) and 301 (k) with respect to male and female hormones. U. S. v. El-O-Pathic Pharmacy, Martin A. Clemens, and Vita Pharmacals, Inc. Tried to the court. Judgment denying application for permanent injunction reversed upon appeal. (Inj. No. 216.)

COMPLAINT FILED: September 2, 1949, Southern District of California, against the El-O-Patic Pharmacy, a corporation, Hollywood, Calif., and Martin A. Clemens, manager. On September 20, 1949, the complaint was amended to include the Vita Pharmacals, Inc., Hollywood, Calif., as a defendant, and to charge Martin A. Clemens as manager of both corporations.

VIOLATION CHARGED: The complaint alleged that the defendants were distributors of certain *male and female hormones;* that the *male hormones* consisted of *methyltestosterone tablets* (10 milligrams and 25 milligrams), *methyltestosterone in linguet form* (5 milligrams and 10 milligrams), and *methyltestosterone combined with vitamin B_1 in linguet form;* and that the *female hormones* consisted of various preparations containing *alpha-estradiol* (ranging from .01 milligram to 0.5 milligram).

The complaint alleged also that the *male and female hormones* were manufactured outside the State of California and were shipped in interstate commerce to the defendants; that during the interstate journey, the drugs bore the legend "Caution: To be dispensed only by or on the prescription of a physician"; and that the defendants repacked and relabeled the drugs and sold and distributed them without a physician's prescription.

The complaint alleged further that the defendants were violating Section 301 (k) of the Act by causing the 5 milligram and 10 milligram *methyltestosterone linguets* to become misbranded while held for sale after shipment in interstate commerce, and that they were violating Section 301 (a) of the Act by causing the introduction into interstate commerce of misbranded 5 milligram and 10 milligram *methyltestosterone linguets* and *methyltestosterone combined with vitamin B_1 in linguet form.*

The above drugs were alleged to be misbranded under Section 502 (f) (1) in that the labeling of the drugs failed to bear adequate directions for use in all conditions for which they were prescribed, recommended, and suggested in the labeling and advertising matter disseminated and sponsored by the defendants, and under Section 502 (f) (2) in that the labeling of the drugs failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form, as are necessary for the protection of the user, since the technical medical terminology in which the labeling of the drugs was couched was inadequate to warn the ordinary lay users that use of the drugs may accelerate the malignant growth of cancer of the prostate gland or may cause sterility.

It was alleged also that the 5 milligram *methyltestosterone linquets* and the *methyltestosterone with vitamin B_1 linguets* were misbranded under Section 502 (a) in that the labeling of such drugs was false and misleading since the labeling represented and suggested that the recommended daily dosage was efficacious for use in the treatment of male hormone deficiency, whereas the recommended daily dosage would be entirely ineffective for such purpose; and that the 10 milligram *methyltestosterone linguets* were misbranded under Section 502 (j) in that such linguets were dangerous to health when used in the